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Prescription Drug Distributors' Facts and Frequently Asked Questions (FAQs)

Drugs and Medical Devices Group investigators perform inspections/investigations of wholesale drug companies, durable medical equipment dealers, and welding supplies. The Texas Administrative Code, Sections 229.251 – 229.254, Licensing of Wholesale Distributors of Drugs; Including Good Manufacturing Practices (Drug Rules), adopts certain federal requirements. For establishments that distribute drugs, of primary importance is Title 21, Code of Federal Regulations, Part 205, Licensing of Wholesale Distributors of Drugs; Including Good Manufacturing Practices (21 CFR, Part 205) -- available at our website or by mail. A major part of your inspection will cover requirements set forth in 21 CFR, Part 205. Below is a listing of some frequently asked questions (FAQs) investigators encounter during inspections of wholesale drug distributors. This is by no means a complete listing of your requirements as a wholesale distributor of drugs.

What written Standard Operating Procedures (SOP's) am I required to maintain?
You are required to maintain all written procedures required in 21 CFR, Part 205 - Section 205.50(g); among these are SOP's for receipt, security, storage, recall, inventory (including correcting all errors and inaccuracies), and distribution of prescription drugs, identifying, recording, and reporting losses or thefts, returns, and disaster preparedness.

Is my facility required to have a temperature monitoring device?
According to 21 CFR, Part 205 – Section 205.50(c), "All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF)." Therefore, you should check the drug labeling for any temperature requirements and, according to Section 205.50(c)(2), if there are requirements, "Appropriate manual, electromechanical, or electric temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs."

Is my facility required to have an alarm system?
According to 21 CFR, Part 205 – Section 205.50(b)(2), "All facilities shall be equipped with an alarm system to detect entry after hours."

What do I do with expired and/or damaged drug products?
According to 21 CFR, Part 205 – Section 205.50(a)(3), "All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed, shall have a quarantine area for storage of prescription drugs that are

outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened."

Who can possess a prescription drug?
Health and Safety Code Chapter 483, Texas Dangerous Drug Act, designates the following persons as authorized to possess a dangerous drug. For complete definitions of each of these terms please refer to the Dangerous Drug Act (available on our website):

- Pharmacies licensed by the Texas State Board of Pharmacy
- Practitioners (for example: medical doctors, dentists)
- Persons who obtain a dangerous drug for lawful research, teaching, or testing, but not for resale
- Hospitals that obtain a dangerous drug for lawful administration by a practitioner
- Officers or employees of the federal, state, or local government
- Manufacturers or wholesalers licensed by the commissioner of health under Chapter 431 (Texas Food, Drug, and Cosmetic Act)
- Carriers or warehousemen
- Home and community support services agencies licensed under and acting in accordance with Chapter 142, Health and Safety Code
- Documented midwifes, (Oxygen U.S.P. only) for use in deliveries
- Persons with a prescription drug, dispensed by a pharmacist, pursuant to a valid prescription

If my firm distributes medical gas cylinders am I required to separate my full cylinders from my empty cylinders?
Yes. According to 21 CFR, Part 205 – Section 205.50(a)(1), "All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed, shall be of suitable size and construction to facilitate cleaning, maintenance, and proper operations." Further, 21 CFR, Part 205 -- Section 205.50(a)(4) states that the facility will "be maintained in a clean and orderly condition." To facilitate proper operations and orderly conditions, your firm must segregate full cylinders from empty cylinders and industrial gases from medical gases if applicable.

What if I also distribute medical devices, such as nebulizers, catheters, and oxygen concentrators? Do I need an additional license?
If your firm distributes medical devices, you will likely need a license to distribute them. You may be eligible for a multiple product license, which is one license that covers multiple activities (distribution of drugs and/or medical devices and/or foods). Check out our website: **www.dshs.state.tx.us/dmd/** or call (512) 834-6626 (Licensing) for more information.

These are only a few FAQs investigators encounter when performing inspections. Feel free to consult our website or contact us (512) 834-6755, for assistance. Someone from the Group is available, Monday through Friday, 8AM to 5PM, to provide you with information and answers to your questions.